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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,871	07/02/2001	Heather A. Bowen-Leaver	2870/485	1385

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EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,871	BOWEN-LEAVER ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11,13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6-11, 13, 15, and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendment filed on February 5, 2004.

Claims 1-3, 5, 6-11, 13, , 15, and 16 are pending. Claim rejections as indicated in the previous Office action dated November 5, 2003 are maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diec (US 6468551 B1).

Diec teaches a W/O microemulsion having finely dispersed oil droplets. See col. 2, lines 15 – 24. The reference teaches that micellar compositions have particle diameters of less than about 100 nm and appear clear and transparent. See col. 2, lines 25 – 27. The reference teaches that oil phase can be hydrocarbon oils, and “furthermore advantagesouly have a content of cyclic linear silicone oils” in addition to other oil phase. See col. 25, lines 48 – 53. Cyclomethicone is particularly mentioned. See col. 25, lines 48 – 53; instant claim 5. The reference teaches that the content of the oily phase range from 0.01-30 % by weight. See col. 25, lines 54 – 56. The reference also teaches that O/W emulsifiers are used in the amount ranging from 0.01-15 % by weight. See col. 25, lines 57 –66. See instant claim 2. The reference also teaches that it is disadvantageous to have high amount of surfactant.

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While the reference fails to teach the "difference in complex viscosity" of the composition, examiner notes that this limitation is a physical property of the claimed composition. Since the prior art teaches the claimed composition obvious, examiner views that the recited physical property is an obvious property of the prior art.

Given the ranges of the oil phase and the emulsifiers in Diec, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have optimized the weight amount of the emulsifiers as suggested by the reference because of an expectation of successfully producing a topical microemulsion gel composition with lesser amount of surfactants.

2. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claudelli (US 4026818) in view of Diec (US 6468551 B1).

Claudelli teaches transparent ringing gels for cosmetic use, comprising mineral oil, water, and 5-9 percent by weight of (2 ethyl 1,3-dihydroxy) 2-propyl oleamide. See col. 1, lines 5 – 63. The reference teaches transparent gels are obtained due to the small particle size of the dispersed droplet, which allows rapid absorption on skin of active ingredients contained in the composition. The reference teaches using low ratios of emulsifier to oil could be achieved, which is less costly. The reference teaches that it is well known in the art that clear ringing gel appeal to consumers. See col. 1, lines 5-9. The reference teaches that minimum of 5 % of emulsifier (2-ethyl-1,3-dihydroxy) and maximum amount of 19.5 % of an oil phase (isostearic acid and mineral oil).

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While the reference fails to teach the 5:1 ratio of oil phase and emulsifier as claimed by applicants, examiner notes that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Claudelli, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. Lowering the concentration of emulsifier is also suggested in the reference.

The reference also fails to teach using silicone oil.

Diec, discussed above, teaches "advantageously" using silicone oil in the oil phase. See col. 25, lines 43-53. The reference also teaches using the emulsifiers and the oily phase within the claimed weigh ratio. The reference also teaches that it is advantageous to have lower amount of emulsifiers.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of Claudelli by adding silicone oil as suggested by Diec because of an expectation of successfully producing an improved cosmetic gel.

3. Claims 7-11, 13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claudelli and Diec, and further in view of Kakoki et al. (U.S. Pat. No. 5,162,377) ("Kakoki").

Claudelli and Diec fail to teach the shearing process of instant claims.

Kakoki teaches the process of making a transparent emulsion cosmetic composition by applying high-shearing treatment to the composition. In the

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reference high shearing force treatment is carried out by high-pressure homogenization using emulsifiers such as Microfluidizer which is used in the present invention, or Manthon Gaulin, under a pressure of 500 psi or more. See col. 4, line 44 – col. 5, line 23. The Examples 4-13 shows treating the emulsion compositions with Manthon Gaulin at least 5-10 times to obtain transparent aqueous compositions.

Given the teaching in the combined references that high-pressure homogenization process is used to produce a nanoemulsion, one of ordinary skill in the art at the time the invention was made to have would have known looked for prior arts such as Kakoki for specific types of homogenizer and method steps to carry out the process to make the said composition, and treated the pre-emulsion with high shearing force to produce transparent compositions.

Response to Arguments

Applicant's arguments filed February 5, 2004 have been fully considered but are unpersuasive.

The claimed composition requires a oil-in-water composition comprising

Applicants argue that the claimed invention is a "ringing nanogel", examiner asserts that claim 1 only requires a composition an oil-in-water composition an oil phase having a mean droplet size of less than "about 100 nm", an emulsifier, a water phase, and a silicone oil component comprising at least one volatile silicone oil different than the oil phase. There is no requirement that the composition be a "ringing" gel. The microemulsion or nanoemulsion gels as taught by Diec also meet the instant limitation because the reference teaches to

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combine silicone oils and particularly cyclomethicone with the oil phase. The reference teaches the overlapping weight range of the oil and emulsifier phases in col. 25, line 65 – col. 26, line 8. The composition is said to have a difference in complex viscosity of at least about 10,000 poise under oscillation stress in the range of “about 0 to 5,000(dyne/cm²)”. The physical property of the composition which is made as taught by the prior art would obviously have the difference in complex viscosity as recited.

Applicants assert that the oil phase and silicone component are “self-structured”. Examiner asserts that there is evidence of record to show that the prior art nanoemulsion gel which is made from the same oil/silicone oils are not somehow not “self-structured” while applicants’ invention is. While applicants argue that the prior art requires a thickener in the composition, examiner respectfully points out that, in the contrary, Diec teaches thickeners are used only “if possible”. Furthermore, examiner takes the position that the claim language of the instant application does not exclude either thickeners or crosslinking agents. The presence of “self-structuring” oil and silicone oil combination as recited in the instant claims does not mean that these are the only components other than water and the emulsifiers in the composition.

In response to applicants’ argument that the Claudelli reference fails to teach the required weight ratio of emulsifier to oil, examiner respectfully points out that the present claims are rejected in view of the collective teachings of the references. Claudelli clearly prefers low amount of emulsifiers, and Diec reference teaches that the oil-in-water dispersion in gel is made with the “lowest

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possible emulsifier content” for cosmetic applications. See col. 5, line 66 – col. 6, line 5. See also col. 24, lines 38 – 59 for the teaching that using high-pressure homogenizer allows making low-emulsifier nanoemulsions and microemulsions.

While applicants argue that Kakoki fails to teach ringing nanogel, examiner again asserts that the argument is an attack against the individual reference. Applicants also assert that the prior art teaches to treat the emulsion with the shearing process at least 5-10 times, while the claimed invention requires the process only twice and trice. Examiner respectfully notes that claim 7 in fact recites “at least 2 times”, and thus the prior art meets this limitation. Claim 8 also recites “wherein the emulsion is subjected to the high shear/pressure treatment three times”. Examiner asserts that the prior art meets that limitation as well because the prior art emulsion is necessarily subjected to the treatment trice during the process of making. Alternatively, it would have been obvious to one of ordinary skill in the art make the emulsion gel in more efficient and less laborious process.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

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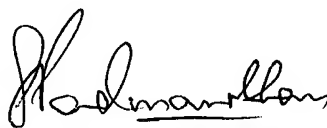
period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



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SUPERVISORY PATENT EXAMINER